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PTO/SB/05 (4/98)  
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# UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 C.F.R. § 1.53(b))

Attorney Docket No. **IAM 0602 PA**  
First Inventor or Application Identifier **Gregory D. Sunvold**  
Title **NUTRITIONAL COMPOSITION FOR WEIGHT MANAGEMENT**  
Express Mail Label No. **EL476648564US**

## APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

## ADDRESS TO:

Assistant Commissioner for Patents  
Box Patent Application  
Washington, DC 20231

1. ☒ \* Fee Transmittal Form (e.g., PTO/SB/17)  
(Submit an original and a duplicate for fee processing)
2. ☒ Specification [Total Pages **12**]  
(preferred arrangement set forth below)  
- Descriptive title of the Invention  
- Cross References to Related Applications  
- Statement Regarding Fed sponsored R & D  
- Reference to Microfiche Appendix  
- Background of the Invention  
- Brief Summary of the Invention  
- Brief Description of the Drawings (if filed)  
- Detailed Description  
- Claim(s)  
- Abstract of the Disclosure
3. ☒ Drawing(s) (35 U.S.C. 113) [Total Sheets **3**]
4. Oath or Declaration (unsigned) [Total Pages **2**]  
a. ☐ Newly executed (original or copy)  
b. ☐ Copy from a prior application (37 C.F.R. § 1.63(d))  
(for continuation/divisional with Box 16 completed)  
i. ☐ DELETION OF INVENTOR(S)  
Signed statement attached deleting  
inventor(s) named in the prior application,  
see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).

5. ☐ Microfiche Computer Program (Appendix)
6. Nucleotide and/or Amino Acid Sequence Submission  
(if applicable, all necessary)  
a. ☐ Computer Readable Copy  
b. ☐ Paper Copy (identical to computer copy)  
c. ☐ Statement verifying identity of above copies

## ACCOMPANYING APPLICATION PARTS

7. ☐ Assignment Papers (cover sheet & document(s))
8. ☐ 37 C.F.R. § 3.73(b) Statement (when there is an assignee) ☒ Power of Attorney
9. ☐ English Translation Document (if applicable)
10. ☐ Information Disclosure Statement (IDS)/PTO-1449 ☐ Copies of IDS Citations
11. ☐ Preliminary Amendment
12. ☒ Return Receipt Postcard (MPEP 503)  
(Should be specifically itemized)
13. ☐ \* Small Entity Statement(s) ☐ Statement filed in prior application, Status still proper and desired (PTO/SB/09-12)
14. ☐ Certified Copy of Priority Document(s) (if foreign priority is claimed)
15. ☒ Other: Check for \$690--filing fee  
Initial Inventor Data Sheet

\* NOTE FOR ITEMS 1 & 13: IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37 C.F.R. § 1.27), EXCEPT IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C.F.R. § 1.28).

16. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No: \_\_\_\_\_  
Prior application information: Examiner \_\_\_\_\_ Group / Art Unit: \_\_\_\_\_

For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 4b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

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Signature	<i>Susan M. Luna</i>	Date	<b>July 5, 2000</b>

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of

Applicant(s): Gregory D. Sunvold

Title : NUTRITIONAL COMPOSITION FOR WEIGHT  
MANAGEMENT

Docket No. : IAM 0602 PA

EL476648564US

BOX PATENT APPLICATION

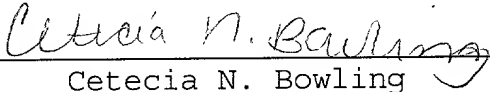
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## Initial Information Data Sheet

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### Application Information

Title Line One:: NUTRITIONAL COMPOSITION FOR WEIGHT  
Title Line Two:: MANAGEMENT  
Total Drawing Sheets:: 3  
Formal Drawings?: No  
Application Type:: Utility  
Docket Number:: IAM 0602 PA

### Representative Information:

Registration Number One:: 26,397  
Registration Number Two:: 27,262  
Registration Number Three:: 29,001  
Registration Number Four:: 39,564  
Registration Number Five:: 38,769  
Registration Number Six:: 33,758  
Registration Number Seven:: 42,695  
Registration Number Eight:: 44,494  
Registration Number Nine:: P-46,867  
Registration Number Ten:: P-46,506

## NUTRITIONAL COMPOSITION FOR WEIGHT MANAGEMENT

## CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. provisional application Serial No. 60/143,032, filed July 9, 1999.

## BACKGROUND OF THE INVENTION

The present invention relates to a nutritional composition for body weight management, and more particularly to such a composition which contains a combination of ingredients which achieve weight loss in a mammal in need of treatment.

Obesity is a relatively common problem in that 30% of the population in the United States is considered to be clinically obese. In dogs and cats, the same problem exists in about 20% of the cats and 40% of dogs. Aside from psychological issues associated with being overweight in humans, humans, as well as dogs and cats that are overweight, can suffer from other physiological disorders such as diabetes, increased blood pressure, increased blood triglycerides, impaired locomotion, skeletal stress, dystocia, thyroid dysfunction, joint problems, and cancers, etc. These statistics demonstrate that obesity is a common problem in dogs, cats, and humans and illustrates the extreme need for technologies which will address and counteract this problem.

In humans, dogs, and cats, current nutritional recommendations often include the recommendation to consume a high fiber diet or foodstuffs that are high in dietary fiber. However, high fiber diets for dogs and cats are often associated with several undesirable side effects including decreased palatability of food, increased stool volume, increased defecation frequency, poor skin and hair, improper mineral balance, and decreased food digestibility. Unfortunately, even though these types of nutritional recommendations have existed for many years, the prevalence of obesity in both humans and pets has continued to increase. The relative abundant access to foods and the dietary habits of the population continues to make it a challenge for humans to

lose weight. Also, because it has been demonstrated that an overweight owner is more likely to have an overweight pet, the prevalence of obesity in dogs and cats has also increased.

Another nutritional recommendation that is often made concerning weight management is to reduce dietary intake of fats. Although numerous low fat, no fat, reduced fat, and "light" types of foodstuffs have appeared and increased their presence in the human food supply, the prevalence of obesity has continued to increase.

Accordingly, there is still a need in the present art to develop a nutritional regimen that assists humans, dogs, and cats in reducing body fat and overall weight.

## SUMMARY OF THE INVENTION

The present invention meets that need by providing a composition which, when fed to an obese or overweight mammal, assists that mammal in losing weight and maintaining the weight loss. The composition may be supplied either in the form of a supplement or as a part of a nutritionally complete diet. By "diet" it is meant the food or drink regularly consumed by the animal.

According to one aspect of the present invention, a composition for promoting weight loss in a mammal is provided comprising effective amounts of at least three nutrients selected from the group consisting of L-carnitine, chromium, Vitamin A, and a source of carbohydrates selected from a low glycemic index grain. In a preferred embodiment, the composition includes a combination of all four nutrients.

Preferably, the composition comprises from about 15 to 195 ppm L-carnitine, from about 10 to about 500 micrograms of chromium, and from about 50,000 IU to about 1,000,000 IU of vitamin A per kilogram of diet.

More preferably, the composition comprises from about 20 to 150 ppm L-carnitine, and most preferably from about 50 to 100 ppm L-carnitine per kilogram of diet.

The composition preferably comprises from about 50,000 IU to about 500,000 IU of Vitamin A per kilogram of diet, and more preferably, from about 50,000 IU to about 150,000 IU of Vitamin A per kilogram of diet.

The source of carbohydrates preferably comprises a low glycemic index grain selected from the group consisting of sorghum, barley, corn, and blends thereof.

The composition also preferably includes from about 18 to 40 wt% crude protein, from about 4 to 30 wt% fat, and from about 2 to 20 wt% total dietary fiber.

5 The composition may be used as a method of promoting weight loss in a mammal in which the mammal is fed a composition containing effective amounts of a combination of at least three nutrients selected from the group consisting of L-carnitine, chromium, Vitamin A, and a source of carbohydrates selected from a low glycemic index grain.

10 The composition is preferably fed in an amount of from about 1.0 to 10.0 mg of L-carnitine per kilogram of body weight per day, from about 5.0 to about 15.0 micrograms of chromium per kilogram of body weight per day, from about 200 to 600 IU of vitamin A per kilogram of body weight per day, and from about 1.0 to 3.0 grams of the carbohydrate source per kilogram of body weight per day.

15 More preferably, the L-carnitine is fed in an amount of from about 2.5 to about 5.0 mg per kilogram of body weight per day.

The present invention provides a multi-nutrient approach for losing weight by addressing the multiple causes for obesity. L-carnitine and/or esters thereof, are included in the composition to provide a means to burn fatty acids. Chromium is provided to improve insulin sensitivity in the mammal which aids the body in storing blood glucose more effectively. Vitamin A is present to reduce leptin levels. Leptin is a hormone that is elevated in mammals that are obese. By reducing leptin, Vitamin A helps to restore the individual to a more normal hormonal status. Reducing starch levels and/or selecting sources of carbohydrates/starches having low glycemic indices improves glucose metabolism of the individual. Improved glucose metabolism results in fewer abrupt rises and drops in blood glucose levels. As a result, the individual feels satiated more often, consumes less food, and loses weight.

25 Accordingly, it is a feature of the present invention to provide a composition which, when fed to an obese or overweight mammal, assists that mammal in losing weight and maintaining the weight loss. This, and other features and advantages of the

30

present invention, will become apparent from the following detailed description, the accompanying drawings, and the appended claims.

### BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a graph comparing body weight loss in canines fed a commercial dietary formulation (diet A) and a composition formulated in accordance with the present invention (diet B);

Fig. 2 is a bar graph illustrating body fat of overweight dogs fed diet A or B;

Fig. 3 is a bar graph illustrating lean body mass of overweight canines fed diet A or B;

Fig. 4 is bar graph illustrating glycemic response of overweight canines after 12 weeks of consuming diet A or B; and

Fig. 5 is a bar graph illustrating glucose metabolism of overweight canines after 12 weeks of consuming diet A or B.

### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The composition of the present invention preferably includes an effective combination of at least three of L-carnitine, chromium, Vitamin A, and a source of carbohydrates having a low glycemic index.

Carnitine may be provided in the composition of the present invention using a source of L-carnitine or a carnitine ester such as carnitine tartrate, carnitine acetate, or carnitine propionate. Dietary supplementation of carnitine in amounts of from between about 15 to about 195 ppm, more preferably between about 20 to about 150 ppm, and most preferably about 50 to about 100 ppm per kilogram of diet, promotes weight loss in overweight mammals. Expressed in another way, carnitine may be fed to the mammal in amounts of from between about 1.0 to about 10.0 mg per kilogram of body weight per day, and preferably about 2.5 to about 5.0 mg per kilogram of body weight per day.

Feeding an effective amount of carnitine to mammals that are overweight results in a greater weight loss than mammals fed a diet containing no supplemental carnitine.

Further, mammals fed a carnitine-supplemented diet exhibit a greater percentage of lean body mass(LBM) than mammals fed the same diet, but with no carnitine supplementation. Also, mammals fed a carnitine-supplemented diet voluntarily restrict their food intake. Reference is also made to co-pending U.S. Patent Application Serial  
5 No. 09/337,938, filed June 22, 1999, and entitled PROCESS AND PRODUCT FOR PROMOTING WEIGHT LOSS IN OVERWEIGHT DOGS, the entire contents of which are hereby incorporated by reference.

The composition of the present invention also preferably contains a source of chromium which has the effect of minimizing the postprandial glycemic and/or insulin  
10 response in a mammal. Chromium may be provided from such bioavailable sources as chromium picolinate, chromium tripicolinate, chromium nicotinate, or chromium yeast. For example, the composition may include chromium tripicolinate in an amount which will provide the mammal with from between about 10 to about 500 micrograms of chromium per day. Expressed in another way, chromium is present in an amount of  
15 from between about 5.0 to about 15.0 micrograms per kilogram of body weight per day. Chromium tripicolinate occurs in brewer's yeast, and the yeast may be added to the composition. Alternatively, the chromium in a substantially-pure bioavailable form may be added directly to the composition.

Vitamin A may be provided in the composition of the present invention as  
20 Vitamin A acetate or retinol, and provides sufficient Vitamin A to result in a reduction in adiposity of the mammal. In addition to reducing adiposity, Vitamin A may also increase UCP1 gene expression, suppress leptin gene expression, and suppress serum leptin levels. This aids in preventing obesity, promoting weight loss, and may also minimize age-related increases in body fat and diabetes-associated increases in body  
25 fat.

The Vitamin A is preferably provided in an amount of about 50,000 IU to about 1,000,000 IU of Vitamin A per kilogram of diet, more preferably, from about 50,000 IU to about 500,000 IU of Vitamin A per kilogram of diet, and most preferably, from about 50,000 IU to about 150,000 IU of Vitamin A per kilogram of diet. Expressed another



way, Vitamin A is supplied in an amount of from between about 200 to about 600 IU per kilogram of body weight per day.

The supplement is preferably fed to a mammal in an amount of about 50,000 IU to about 1,000,000 IU of Vitamin A per day (based on a diet of 1,000 g per day), or about 5,000 IU to about 100,000 IU of Vitamin A per day (based on a diet of 100 g per day). Reference is also made to co-pending U.S. Patent Application Serial No. 09/288,873, filed April 9, 1999, and entitled PROCESS FOR DECREASING ADIPOSITY USING VITAMIN A AS A DIETARY SUPPLEMENT, the entire contents of which are hereby incorporated by reference.

The present invention also preferably includes a source of carbohydrates from a low glycemic index grain. Glycemic index is a measure of the rate at which carbohydrates are broken down into glucose and absorbed by the bloodstream. Glycemic index is a relative scale measured from a reference standard food (normally 50 gm white bread = 100). By "low glycemic index" it is meant that the starch source provides a glycemic response which is closer to fasting glucose and insulin levels than a reference standard carbohydrate source. Suitable low glycemic index grains include sorghum, barley, corn, and blends thereof. Brewer's rice is not a suitable grain source for the present invention. The invention may also use multiple grains comprising a blend of sorghum and barley; a blend of corn and barley; a blend of corn and sorghum; or a blend of corn, sorghum, and barley. Preferably, the weight ratio of grain sources in any blends is from about 1:5 to about 5:1, and more preferably the weight ratio of any blends contains substantially equal amounts of each grain (i.e., a 1:1 ratio). Where a combination of three grain sources is used, the weight ratios of the lowest to highest amount of grain source will vary between from about 1:1 to about 5:1. The composition of the present invention includes an amount of these starch sources to provide a mammal with from about 1.0 to about 3.0 grams of starch per kilogram of body weight per day. Reference is also made to co-pending U.S. Patent Applications Serial Nos. 09/055,538, filed April 6, 1998, and entitled COMPOSITION AND PROCESS FOR IMPROVING GLUCOSE METABOLISM IN COMPANION ANIMALS, and 60/121,087, filed February 23, 1999, and entitled ALTERATION OF GLUCOSE METABOLISM IN

COMPANION ANIMALS BY DIETARY STARCH, the entire contents of which are hereby incorporated by reference.

5 The nutrients described above may be provided in any suitable formulation which also provides adequate nutrition for the mammal, such as a supplement in the form of a pill or capsule, or a pet food composition. For example, a composition for use in the present invention may contain about 18-40 wt% crude protein, about 4-30 wt% fat, and about 2-20 wt% total dietary fiber. However, no specific percentages or ratios are required. Preferably, the mammal is fed a low-fat carnitine-supplemented diet to promote weight loss. A typical low-fat diet may contain about 21.1 wt% protein, about 10 8.6 wt% fat, and about 1.7 wt% crude fiber.

In order that the invention may be more readily understood, reference is made to the following example which is intended to illustrate the invention, but not limit the scope thereof.

#### Example 1

15 Twenty adult female Beagle dogs were used to evaluate the effects of a multi-nutrient approach to weight loss. Fresh water was provided ad libitum during the entire study. Food was provided ad libitum during both the weight gain and weight loss phases of the study.

20 The study consisted of two periods: weight gain and weight loss. During the 10-week weight gain period, all dogs were fed a high-protein, high fat diet (Purina® Pro-Visions ProPlan® Chicken and Rice Performance Formula (about 35% protein, 23% fat, and 2% crude fiber). At the initiation of the weight loss period, the dogs were stratified by body weight, percent body fat, and blood glucose and then randomly assigned to 2 dietary treatment groups of 10 dogs each. Group A dogs were fed a traditional, high 25 fiber diet (Hill's® Prescription Diet® w/d® Canine) (diet A) and Group B dogs were fed a diet formulated in accordance with the present invention (Eukanuba Veterinary Diets® Nutritional Weight Maintenance Formula™ Glucose-Control™/Canine (diet B) ad libitum.

The composition of the diets (on a dry matter basis) is shown below in Table 1.

Table 1

		<u>Diet A</u>	<u>Diet B</u>
5	Protein %	16	28.8
	Fat %	9.7	7.8
	Ash %	4.2	7.2
	Crude fiber %	17.0	3.7
	Carnitine (ppm)	250	60
10	Gross Energy, Kcal/g	4.743	4.604
	Megabolizable Energy	3.244	3.509
	% of calories from:		
	Protein	17.4	28.7
	Carbohydrates	57.2	52.4
15	Fat	25.4	18.9

Diet B also contained amounts of chromium (chromium tripicolinate) and a blend of sorghum and barley as the carbohydrate source in accordance with the present invention.

Food intake and body weight were monitored daily and weekly, respectively. Whole body composition was determined at the initiation and termination of the weight loss period. Whole body composition was determined using dual energy x-ray absorptiometry (DEXA) and Hologic QDR-2000 Plus High Resolution X-Ray Bone Densitometer.

After 14 weeks of feeding diets A and B, a glucose tolerance test was performed. (Serum glucose and insulin concentrations were determined from blood obtained at 0, 2, 4, 6, 8, 10, 12, 14, 16, 19, 22, 25, 30, 40, 50, 60, 70, 80, 90, 100, 120, 140, 160 and

180 min. after administering 300 mg/kg BW glucose at time 0 and 0.02 U/kg BW insulin at time 20 min.

### Statistical Analysis

5 A repeated measures analysis was used for the statistical analysis. The model statement included the following variables: diet, time, diet x time and animal within treatment and error. The least significant difference test of the General Linear Models procedure in SAS (SAS, 1996), was used to compare means between diets within time period.

### Results

10 Under ad libitum feeding conditions, dogs fed diet A and diet B lost a similar amount of body weight as shown in Fig. 1. However, dogs fed diet B lost more body fat than dogs fed diet A. Dogs fed diet B also tended to accumulate lean body mass while dogs fed diet A maintained lean body mass (see Fig. 3).

15 Dogs fed diet B also had a numerically more favorable insulin sensitivity than dogs fed diet A (see Fig. 4). Dogs fed diet B also had a more optimal glucose effectiveness than dogs fed Diet A (see Fig. 5).

These results indicate that the multi-nutrient composition of the present invention provides a more preferable weight loss compared to a traditional high fiber diet.

20 While certain representative embodiments and details have been shown for purposes of illustrating the invention, it will be apparent to those skilled in the art that various changes in the methods and apparatus disclosed herein may be made without departing from the scope of the invention, which is defined in the appended claims.

What is claimed is:

## CLAIMS

1. A composition for promoting weight loss in a mammal comprising effective amounts of at least three nutrients selected from the group consisting of L-carnitine, chromium, Vitamin A, and a source of carbohydrates selected from a low glycemic index grain.
2. A composition for promoting weight loss in a mammal comprising effective amounts of L-carnitine, chromium, Vitamin A, and a source of carbohydrates selected from a low glycemic index grain.
3. The composition of claim 1 comprising from about 15 to 195 ppm L-carnitine, from about 10 to about 500 micrograms of chromium, and from about 50,000 IU to about 1,000,000 IU of vitamin A per kilogram of diet.
4. The composition of claim 1 comprising from about 20 to 150 ppm L-carnitine.
5. The composition of claim 1 comprising from about 50 to 100 ppm L-carnitine.
6. The composition of claim 1 comprising from about 50,000 IU to about 500,000 IU of Vitamin A per kilogram of diet.
7. The composition of claim 1 comprising from about 50,000 IU to about 150,000 IU of Vitamin A per kilogram of diet.
8. The composition of claim 1 wherein said source of carbohydrates comprises a grain selected from the group consisting of sorghum, barley, corn, and blends thereof.
9. The composition of claim 1 further including from about 18 to 40 wt% crude protein, from about 4 to 30 wt% fat, and from about 2 to 20 wt% total dietary fiber.

10. A process for promoting weight loss in a mammal comprising the step of feeding said mammal a composition containing effective amounts of a combination of at least three nutrients selected from the group consisting of L-carnitine, chromium, Vitamin A, and a source of carbohydrates selected from a low glycemic index grain.

5 11. The process of claim 10 in which said composition is fed to said mammal in an amount of from about 1.0 to 10.0 mg of L-carnitine per kilogram of body weight per day, from about 5.0 to about 15.0 micrograms of chromium per kilogram of body weight per day, from about 200 to 600 IU of vitamin A per kilogram of body weight per day, and from about 1.0 to 3.0 grams of starch per kilogram of body weight per day.

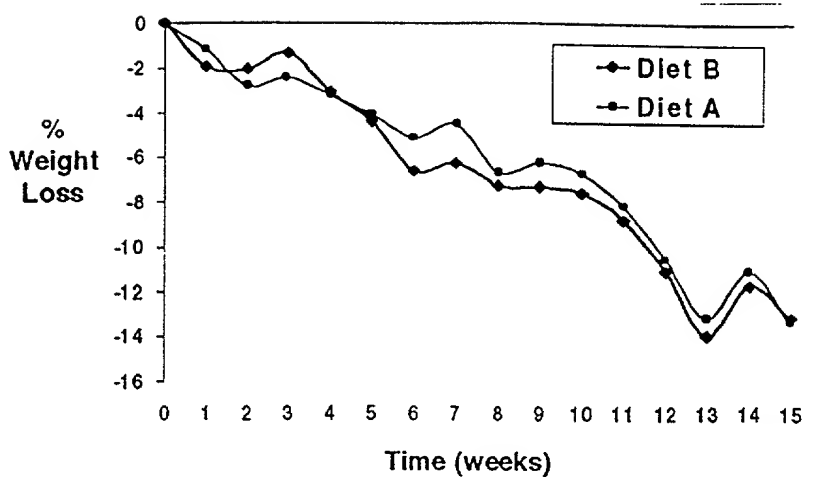
10 12. The process of claim 11 wherein said L-carnitine is fed to said mammal in an amount of from about 2.5 to about 5.0 mg per kilogram of body weight per day.

13. The process of claim 10 wherein said source of carbohydrates is selected from the group consisting of sorghum, barley, corn, and blends thereof.

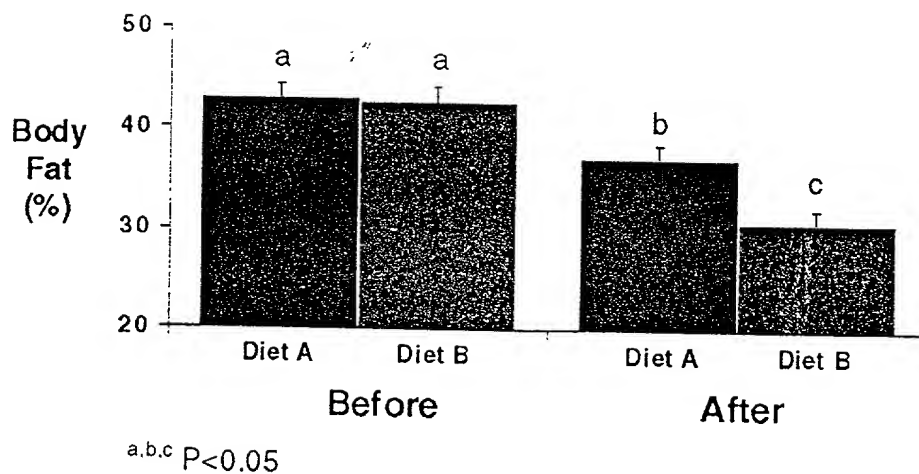
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**Figure 1**  
Body weight  
loss of  
overweight  
canines fed  
diet A or B.

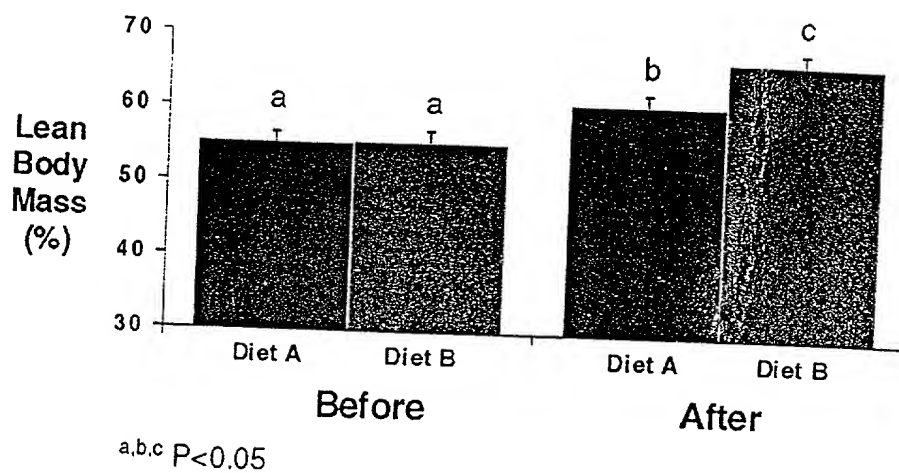


**Figure 2**  
Body fat of  
overweight  
canines fed  
diet A or B.

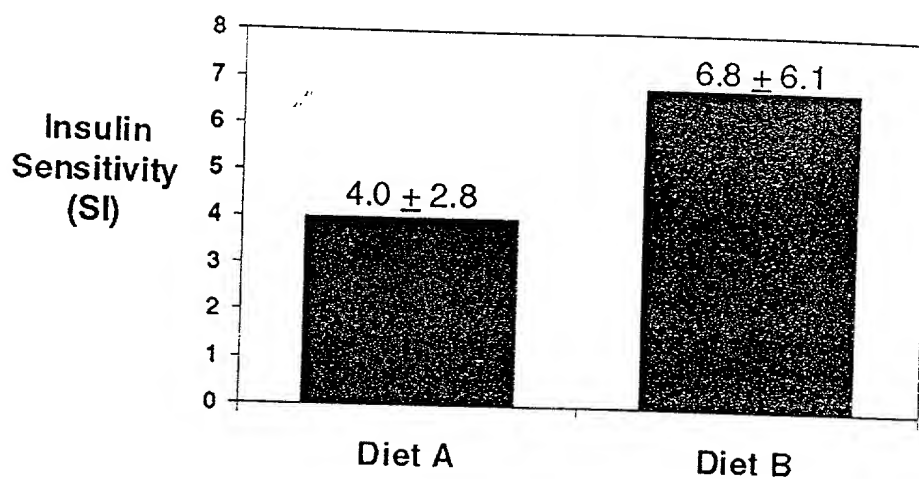




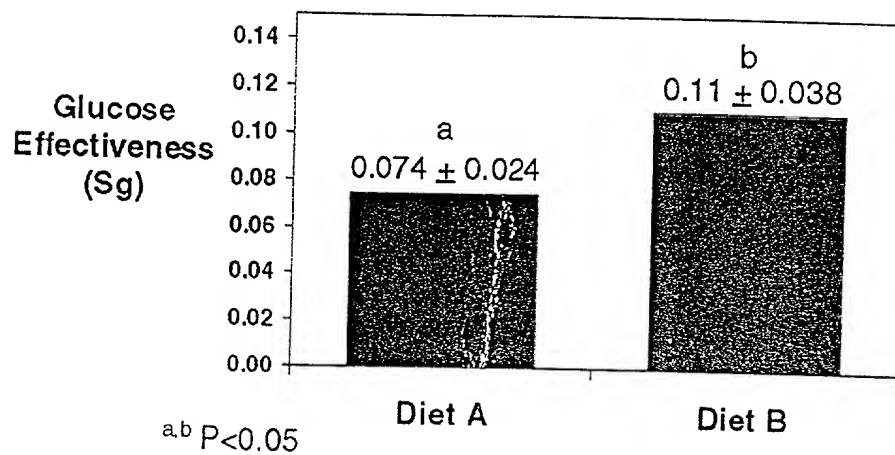
**Figure 3**  
Lean body mass of overweight canines fed diet A or B.



**Figure 4**  
Glycemic response of overweight canines after 12 weeks of consuming diet A or B.



**Figure 5**  
Parameters of  
glucose  
metabolism  
after 12 weeks  
of consuming  
diet A or B.



DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the invention entitled:

**NUTRITIONAL COMPOSITION FOR WEIGHT MANAGEMENT** (Docket No. IAM 0602 PA), described and claimed

  X   in the attached specification;  
       in the specification filed \_\_\_\_\_, as U.S. Application Serial No. \_\_\_\_\_, and as amended \_\_\_\_\_.

I hereby authorize the attorney(s) and/or agent(s) appointed herein to indicate above whether the invention is described and claimed in an attached specification and to provide the Filing Date and Serial No. of the corresponding U.S. Application, if previously filed.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims as filed and as amended by any amendment referred to above.

I acknowledge the duty to disclose to the Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim the benefit under 35 USC § 119(e) of any United States provisional application(s) listed below:

Application Number	Filing Date
<u>60/143,032</u>	<u>July 9, 1999</u>

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

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I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

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